IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., and NOVOPHARM, LTD., Counterclaim Plaintiffs, v. ABBOTT LABORATORIES, FOURNIER INDUSTRIE ET SANTÉ, and LABORATOIRES FOURNIER S.A., Counterclaim Defendants.	C.A. No. 02-1512 (SLR) CONSOLIDATED
IMPAX LABORATORIES, INC., Counterclaim Plaintiff, v. ABBOTT LABORATORIES, FOURNIER INDUSTRIE ET SANTÉ, and LABORATOIRES FOURNIER S.A., Counterclaim Defendants.	C.A. No. 03-120 (SLR) CONSOLIDATED
IN RE TRICOR DIRECT PURCHASER ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	C.A. No. 05-340 (SLR) CONSOLIDATED
IN RE TRICOR INDIRECT PURCHASER ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	C.A. No. 05-360 (SLR) CONSOLIDATED

DEFENDANTS' MOTION FOR LEAVE TO FILE A
MOTION FOR SUMMARY JUDGMENT ON ANTITRUST INJURY

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Dated: April 18, 2008

BACKGROUND

The Court's Order of April 3, 2008 permitted summary judgment motions to be submitted on two antitrust issues: market definition and the propriety of the patent litigations. Defendants seek leave to address an additional antitrust issue.[1] The legal issue is whether Plaintiffs have suffered "antitrust injury" as a result of Defendants' new product introductions and old product discontinuances, which form the core of Plaintiffs' antitrust allegations.

The undisputed facts demonstrate that Plaintiffs cannot satisfy this essential element of their antitrust claims. As such, all of Plaintiffs' federal and state claims relating to Defendants' introduction of new products and discontinuance of old products from the market are ripe for disposition and should be resolved on summary judgment. Under the circumstances, leave to file the proposed motion is warranted. *See Capital Imaging Assocs. v. Mohawk Valley Med. Assocs.*, 996 F.2d 537, 541 (2d Cir. 1993) (summary judgment is "a vital procedural tool to avoid wasteful trials and may be particularly important in antitrust litigation to prevent lengthy and drawn-out litigation that has a chilling effect on competitive market forces"); *see also McGahee v. N. Propane Gas Co.*, 858 F.2d 1487, 1493 (11th Cir. 1988) ("[S]ummary judgment may be especially appropriate in an antitrust case.").

Defendants do not propose to retread ground already covered in Judge Jordan's May 26, 2006 Order on Defendants' motion to dismiss. In ruling on Defendants' motion to dismiss, Judge Jordan necessarily had to accept Plaintiffs' allegations as true. Among those allegations, and key to Judge Jordan's decision, was the claim that consumers were not presented with a choice between fenofibrate formulations. *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F.

[1] Defendants are also filing a motion for leave to file a motion for summary judgment on certain Plaintiffs' state law claims.

Supp. 2d 408, 422 (D. Del. 2006) ("[A]ccording to Plaintiffs, consumers were not presented with a choice between fenofibrate formulations."). Relying in part on this allegation in Plaintiffs' complaint, Judge Jordan found that Plaintiffs had stated a claim that Defendants, by their conduct, foreclosed substantially all competition in what Plaintiffs deem to be the relevant market. *Id.* at 423.[2]

Discovery in this case has revealed the following undisputed facts: from May 2002 (a) every physician in the United States had the opportunity to choose from among the fenofibrate products of Defendants, Teva and, thereafter, Impax and other non-party manufacturers and (b) end-payors (either patients or their insurers and managed care plans) similarly could choose among the fenofibrate products of these manufacturers. In fact, insurers and managed care plans could (and sometimes did) give preferential treatment to other fenofibrate products over TriCor through formulary plans.

Plaintiffs' antitrust claims seeking to condemn Defendants' introduction of new products and withdrawal of older formulations are, therefore, fatally flawed in that Defendants' alleged actions expanded and did not limit consumer choice. The Manufacturer Plaintiffs (as well as other manufacturers) were free to enter the market, and in fact did so, and physicians were able to choose from among their products. Defendants did not prevent competitors from bringing to market copies of their old product formulations (or selling other fenofibrate formulations) and in fact *expanded* the choices available to consumers by introducing new

[2] Defendants accept plaintiffs' relevant market for purposes of this proposed motion only. Defendants' proposed "antitrust injury" summary judgment motion would be independent of their motion on market definition. Although Defendants believe this case is amenable to summary judgment on the issue of market definition, Defendants assume, for the purposes of this motion only, a "fenofibrate molecule" relevant market as alleged by most Plaintiffs.

product formulations. To the extent Plaintiffs suffered any injury as a result of the Manufacturer Plaintiffs' inability to effect automatic generic substitution of their products for Defendants' new formulations, that injury flows not from Defendants' conduct, but from constraints built into the regulatory scheme governing generic substitution. As such, Plaintiffs cannot demonstrate "antitrust injury" and their antitrust claims must be dismissed as a matter of law.

SUMMARY OF PROPOSED ARGUMENT

Plaintiffs allege that there is a relevant product market limited to pharmaceutical products containing the fenofibrate molecule and that, after April 2002, defendants foreclosed competition in the so-called fenofibrate molecule market. The purported foreclosure was allegedly effected by: (a) "sham litigation" by Defendants against the generic manufacturer Plaintiffs,[3] (b) Defendants' introduction of new formulations of their product, TriCor, and (c) Defendants' discontinuance of their old fenofibrate products. According to Plaintiffs, because physicians shifted from prescribing the old TriCor formulation to prescribing the new one, Plaintiffs could not take advantage of state generic substitution laws that permit pharmacists to dispense AB-rated generic drugs in place of the "brand name" drug unless directed not to do so by the prescribing physician. However, because no antitrust injury flowed from Defendants' introduction of new formulations and withdrawal of old products, Defendants respectfully request leave to file a summary judgment motion. The reasons supporting Defendants' request are set forth in more detail below.

[3] Defendants will address Plaintiffs' "sham litigation" claim in a separate summary judgment motion, which was authorized by the Court's April 3, 2008 Order.

I. ANTITRUST INJURY

A plaintiff seeking damages for an antitrust violation must demonstrate "antitrust injury," which is "injury of the type the antitrust laws were intended to prevent and that flows from that which makes the defendant's acts unlawful." *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 334 (1990); *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). It is not enough for Plaintiffs to show that they have been disadvantaged by Defendants' alleged actions. They must show that their injuries are the result of anticompetitive conduct by the Defendants, and are not the result of the limitations on generic substitution under the generic substitution regulatory scheme. *See, e.g., City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 265 (3d Cir. 1998) (City suffered no antitrust injury because "any injury suffered by the City did not flow from the defendants' conduct, but, rather, from the realities of the regulated environment in which all three were actors"); *In re Canadian Imp. Antitrust Litig.*, 470 F.3d 785, 791 (8th Cir. 2006) (affirming dismissal of complaint where plaintiffs' injury was caused by the FDA's importation restrictions and not defendants' conduct).

A recent decision by the District of Columbia District Court in *Walgreen Company v. AstraZeneca Pharmaceuticals L.P.* (the "*Nexium*" case), is instructive as it addressed allegations nearly identical to Plaintiffs' claims and found that the *Nexium* defendant's actions were not exclusionary and plaintiffs there had not suffered "antitrust injury." 534 F. Supp. 2d 146 (D.D.C. 2008).

II. THE *NEXIUM* CASE CLEARLY SUPPORTS DEFENDANTS' REQUEST

The district court in the *Nexium* case applied the antitrust injury doctrine to similar facts on a motion to dismiss and dismissed claims similar to those alleged by Plaintiffs in the instant case. Defendants' proposed motion would demonstrate that a similar result is warranted on the facts of this case.

In *Nexium*, pharmacy chains and others – including many of the Plaintiffs in this case – complained that the brand manufacturer (AstraZeneca) switched an alleged market for a brand drug ("Branded Prilosec") used to treat heartburn and related conditions to AstraZeneca's new – but allegedly "virtually identical" – brand drug (Nexium) and AstraZeneca's over-the-counter Prilosec ("OTC Prilosec"). *Id.* at 148-49. The "switch" occurred at the time generic manufacturers were about to gain FDA approval to copy Branded Prilosec and market an AB-rated generic product ("AB-Rated Generic Prilosec"). *Id.* AstraZeneca promoted Nexium very aggressively, and simultaneously ceased promoting and detailing Branded Prilosec completely. *Id.* The result, not surprisingly, was that many physicians stopped prescribing Branded Prilosec and began prescribing Nexium, which could not be copied because it was under patent.

Plaintiffs' theory was simple. If Nexium had not been introduced and AstraZeneca had not aggressively convinced physicians to switch from Branded Prilosec to Nexium, physicians would have continued to prescribe Branded Prilosec and the prescriptions would have been filled with AB-Rated Generic Prilosec. *Id*. at 149. ("Plaintiffs also project that if Nexium had not gone to market, the manufacturers of generic substitutes to prescription Prilosec would have far more than their current 30% of the market, and consumers would have collectively saved $11.5 billion by the end of the year 2006.") Plaintiffs even characterized the

switch that frustrated their plans for a free ride as based on "distortion and misdirection in marketing, promoting and detailing Nexium." *Id.*

The *Nexium* court dismissed plaintiffs' complaint on two grounds: (1) that Astrazeneca's alleged exclusionary conduct did not violate the antitrust laws, and (2) alternatively, that the alleged losses plaintiffs suffered were not "antitrust injury." *Id.* at 151-52. That analysis is dispositive here.

III. PLAINTIFFS' ANTITRUST CLAIMS BASED ON THE "INTRODUCTION OF NEW FORMULATIONS" CANNOT WITHSTAND SUMMARY JUDGMENT

Plaintiffs' claim that Defendants violated the antitrust laws through their introduction of two new formulations of TriCor is squarely rejected by the *Nexium* court. As noted above, the plaintiffs in the *Nexium* case (many of whom are also Plaintiffs here) alleged that Nexium was "virtually identical to and no more effective than" the product already on the market. *Id.* at 150.

In this case, Plaintiffs make precisely the same argument as to the new TriCor formulations. The *Nexium* court held that the introduction of such new products is not an "exclusionary" act under the antitrust laws and could not cause "antitrust injury." *Id.* at 151-52. Specifically, "introducing a new competitive product and successfully competing in marketing the new product" could not inflict "antitrust injury." *Id.* at 152. Similarly, in this case, Defendants' decision to introduce their new products, like the new product introduction in the *Nexium* case, could not have caused Plaintiffs "antitrust injury" here. For the purposes of its proposed "antitrust injury" summary judgment motion, Defendants do not need, or intend to, offer evidence of whether their new formulations were "improvements." Defendants' proposed motion presents a purely legal argument supported by undisputed facts concerning the existence of consumer choice and is perfectly suited for summary judgment. *Grumman Allied Indus., Inc.*

v. Rohr Indus., Inc., 748 F.2d 729, 739 (2d Cir. 1984) ("Summary judgment is appropriate where the factual predicates of each legal question are undisputed.").

IV. DEFENDANTS' ALLEGED "WITHDRAWAL AND DELISTING" OF TRICOR SIMILARLY DID NOT INFLICT "ANTITRUST INJURY"

Plaintiffs will contend that it is the combination of the withdrawal of old formulations of TriCor from the market along with introduction of new TriCor formulations that makes their claim cognizable under the antitrust laws and distinguishes this case from the *Nexium* case. *Walgreen Co.*, 534 F. Supp. 2d at 151. But this purported distinction falls away upon an examination of the undisputed facts. Indeed, although the *Nexium* court did distinguish the motion to dismiss ruling in this case, it did so on the basis of Plaintiffs' then-untested allegations that Defendants' actions eliminated consumer "choice" in the so-called fenofibrate market. As the undisputed facts will show, there was, in fact, choice.

The undisputed facts of this case establish that other fenofibrate products in fact came on the market and that consumers therefore were free to choose between 200 mg. capsules (manufactured by Teva) and TriCor 160 mg. tablets, and later were free to choose between Teva's 200 mg. capsules, TriCor 145 mg. tablets and the various fenofibrate products of non-party manufacturers. If physicians wished to do so, they were free to write prescriptions for 200 mg. fenofibrate formulations offered by other manufacturers.

That choice is no different than the choice that existed in *Nexium*, where physicians remained free to write prescriptions for Branded Prilosec or AB-Rated Generic Prilosec. Similarly, the record shows insurers have been (and continue to be) free to give preference to fenofibrate products other than TriCor. Nothing stopped the other fenofibrate manufacturers from promoting their products, and nothing stops physicians, insurers, or other managed care organizations from favoring other fenofibrate products over Defendants' products.

The fact that AstraZeneca continued to sell (but not promote) its old product (Branded Prilosec) whereas Defendants discontinued their old TriCor product does not alter the antitrust analysis. The *Nexium* court's alternative holding that plaintiffs had not suffered "antitrust injury" applies equally where (1) sales of the reference-listed drug (Branded Prilosec) otherwise available for generic substitution are "siphoned off" to a significant degree by aggressive marketing of a new product and effective abandonment of an old product; and (2) sales of the reference-listed drug (old TriCor formulation) drop off entirely by aggressive marketing and subsequent discontinuance of the old product but other forms of the same formulation can and do populate the market. *Id.* at 152 ("The fact that a new product siphoned off some of the sales from the old product and, in turn, depressed sales of the generic substitutes for the old product, does not create an antitrust cause of action.").

In both situations, generic sales based on automatic substitution are depressed by a downturn in physicians' writing prescriptions of the original branded product (Branded Prilosec or, in the present case, the old formulation of TriCor). In both situations, Defendants' action in introducing new products, even if it involves withdrawing an old product, is pro-competitive in providing greater choice and does not inflict the type of injury the antitrust laws were designed to prevent.

Defendants will further demonstrate that, to the extent Plaintiffs complain about their inability to gain a greater share of the market due to their inability to achieve generic substitution for Defendants' new products, it is the result of the regulatory framework that limits pharmacy substitution to generic drugs that are AB-rated to the reference-listed drug at the time the generic files its ANDA (and does not authorize substitution under other circumstances).

As Plaintiffs readily admit, a generic manufacturer's preferred business scenario is (a) to copy a branded product in every particular – e.g., dosage (number of milligrams) and dosage form (capsule or tablet) (an "AB-rated generic product") – and (b) then sit back and rely on state substitution laws that either mandate or allow a pharmacist to substitute an AB-rated generic drug when a physician writes a prescription for the branded product. By taking a free ride on a brand manufacturer's development of its branded product and the brand manufacturer's investment in educating physicians about the product, generic manufacturers avoid investment in new product development and physician education. But nothing in the antitrust laws (or the Hatch-Waxman Act) entitles Plaintiffs to a static market, and as the *Nexium* decision demonstrates, brand manufacturers do not inflict antitrust injury by moving demand to new products or formulations. The loss of a free-ride through AB-rated generic substitution does not constitute antitrust injury. If Plaintiffs were injured, "it was not 'by reason of anything forbidden in the antitrust laws.'" *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. at 488.

CONCLUSION

For the foregoing reasons, Defendants respectfully request permission to file a motion for summary judgment pursuant to Rule 56 on the issue of "antitrust injury."

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Dated: April 18, 2008
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RULE 7.1.1 CERTIFICATION

I hereby certify that counsel for defendants have raised the subject of the foregoing motion with counsel for the plaintiffs, and that the parties have not been able to reach agreement on the issues raised in the motion

Dated: April 18, 2008

/s/ James W. Parrett, Jr.
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on April 18, 2008, the foregoing was caused to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

In addition, the undersigned hereby certifies that true and correct copies of the foregoing were caused to be served via electronic mail on April 18, 2008 upon the following parties:

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